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February 4, 2022

The Honorable Patty Murray
United States Senate
154 Russell Senate Office Building
Washington, D.C 20510

The Honorable Richard Burr
United States Senate
217 Russell Senate Office Building
Washington, D.C 20510

Dear Chair Murray and Ranking Member Burr:

On behalf of the Infectious Diseases Society of America (IDSAs), thank you for authoring the discussion draft of the Prepare for and Respond to Existing Viruses, Emerging New Threats and Pandemics Act (PREVENT Pandemics Act) and for the opportunity to provide feedback on that draft. IDSAs represents more than 12,000 infectious diseases physicians, scientists and other public health and health care professionals on the frontlines of the COVID-19 pandemic. We are pleased to support many provisions in your discussion draft, as detailed below.

The success of many efforts outlined in your discussion draft will hinge upon all communities having access to an expert health care workforce focused on biopreparedness and infectious diseases. In addition, more must be done to address the global health threat of antimicrobial resistance. Therefore, we strongly urge you to include the following bipartisan legislation, priorities for IDSAs, in the PREVENT Pandemics Act:

Bolstering Infectious Outbreaks (BIO) Preparedness Workforce Act (S. 3244) introduced by Senators Tammy Baldwin (D-WI), Susan Collins (R-ME), Jacky Rosen (D-NV) and Lisa Murkowski (R-AK) to address the significant workforce shortages and recruitment challenges currently facing physicians, pharmacists, laboratory professionals, infection preventionists, advanced practice nurses, physician assistants and dentists who primarily work in biopreparedness or who provide infectious diseases care in underserved settings and designated shortage areas.

Pioneering Antimicrobial Solutions to End Upsurging Resistance (PASTEUR) Act (S. 2076) introduced by Senators Michael Bennet (D-CO) and Todd Young (R-IN) to revitalize the antibiotic pipeline and strengthen our hospitals' antibiotic stewardship programs to ensure those novel antibiotics are brought to market and that their effectiveness is safeguarded. We urge you to expand the discussion draft's approach to antimicrobial resistance (AMR)—considered by the World Health Organization, Centers for Disease Control and Prevention (CDC) and other medical and public health experts to be a major global health threat.

Below is a summary overview of our recommendations on the discussion draft. Also, attached are our detailed section-by-section comments, including discussion of sections that IDSA supports. We welcome the opportunity to collaborate with you in your ongoing efforts to strengthen our nation's preparedness for pandemics and other infectious diseases threats.

SUMMARY OF RECOMMENDATIONS

Title I: Subtitle A—Federal Leadership and Accountability

- Explicitly include representatives from underserved populations in the composition of the Public Health Information and Communications Advisory Committee (pages 42-43).
- Require the Advisory Committee, as part of its recommendations/report, to document any new resources or authorities needed to implement planned actions (pages 41-42).

Title I: Subtitle C—Revitalizing the Public Health Workforce

- Include the Bolstering Infectious Outbreaks (BIO) Preparedness Workforce Act (S. 3244).

Title III: Sec. 304. Accessing specimen samples and diagnostic tests.

- Add “, **including academic clinical laboratories,**” as an example of an appropriate entity that HHS may partner with (page 125, line 23 – inserted after “appropriate entities”).

Title V—Enhancing Development and Combating Shortages of Medical Products

- Include the Pioneering Antimicrobial Solutions to End Upsurging Resistance (PASTEUR) Act (S. 2076).

Once again, IDSA thanks you for your leadership in authoring the PREVENT Pandemics Act and for the opportunity to provide feedback on the discussion draft. If you have any questions or if we may assist you in any way, please contact Amanda Jezek, IDSA senior vice president for public policy and government relations, at ajezek@idsociety.org.

Sincerely,



Daniel P. McQuillen, MD, FIDSA

President, IDSA

SECTION-BY-SECTION COMMENTS ON THE PREVENT PANDEMICS ACT DISCUSSION DRAFT

Title I—Strengthening Federal and State Preparedness

Subtitle A—Federal Leadership and Accountability

Sec. 101. Comprehensive review of the COVID-19 response. IDSA supports this provision and believes that such a review of the COVID-19 response will allow us to better apply lessons learned from the current pandemic to improve our preparedness and response to future events. We appreciate that the task force created by this section would include individuals with expertise in medicine, public health and research, as these disciplines are on the frontlines of the COVID-19 response and will be able to provide candid, direct perspectives and expertise to this review.

Sec. 103. Public health and medical preparedness and response coordination. IDSA supports this section. Increasing coordination across federal agencies should help streamline response activities and reduce the potential for confusion. Regular preparedness exercises and congressional hearings on preparedness will help ensure this important issue remains at the forefront of our national agenda, strengthening our vigilance against future threats. IDSA notes that we are experiencing serious shortages of the very professionals needed to conduct preparedness exercises at health care facilities – physicians, pharmacists, clinical laboratory personnel, advanced practice nurses, physician assistants and infection preventionists. **We urge you to include in the PREVENT Pandemics Act a provision designed to address these workforce shortages. As noted above, we believe that inclusion of the BIO Preparedness Workforce Act would strengthen your bill as the success of many of these activities depends on an adequate infectious diseases workforce in the community.**

Sec. 104. Strengthening public health communication. IDSA supports this section to establish a Public Health Information and Communication Advisory Committee. Confusing messages, misinformation and disinformation pose significant challenges to pandemic preparedness and response and have fueled vaccine hesitancy and lack of public cooperation with public health guidelines, such as masking. IDSA appreciates that individuals with expertise in public health and medicine would be included in the advisory committee. **We recommend that Congress explicitly direct the Secretary to also include individuals from underserved populations – including African American/Black, Latinx, Indigenous and rural communities – in the Advisory Committee (pages 42-43).** These populations are disproportionately impacted by COVID-19, and unique communications approaches may be necessary to build trust in communities that have been historically marginalized. We appreciate that the Secretary would be directed to submit a report describing any actions planned by the Secretary related to the communication and dissemination of scientific and evidence-based public health information. **IDSA recommends that the Advisory Committee also be required to document any new resources or authorities needed to implement planned actions as part of the mandated recommendations and report (pages 41-42).** Finally, IDSA notes that numerous studies have found that an individual's own health care providers are among the most trusted messengers for public health communications. Shortages of providers leave many communities without expert messengers to implement communications strategies, and IDSA strongly encourages you to address these workforce shortages.

Subtitle B—State and Local Readiness

Sec. 111. Improving state and local public health security. IDSA supports this section to strengthen coordination on public health emergency preparedness, particularly with school systems. Over the course of the COVID-19 pandemic, we learned effective strategies to facilitate in-person learning while preventing transmission of COVID-19, and we saw the negative effects on children when in-person learning was halted. We further saw the important roles schools can play as community hubs to facilitate vaccination. All of these experiences underscore the importance of including school systems in public health emergency planning.

Sec. 114. Assessment of containment and mitigation of infectious diseases. IDSA supports this section, which represents another important opportunity to assess lessons learned from the COVID-19 pandemic, including specifically on isolation and quarantine. Early in the pandemic, state and local public health departments had very little warning to prepare to receive and manage quarantined travelers. Isolation and quarantine preparedness is one of the most challenging aspects of public health emergency response planning. It is highly resource-intensive and complex, requiring coordination of overlapping authorities across various levels of government, and complicated and resource-intensive public health and health care system activities. There are major logistical challenges and costs associated with finding suitable isolation and quarantine facilities, meeting the needs of the population under isolation or quarantine, monitoring their health and ensuring timely medical evaluation and testing when necessary, including safe and secure transport from isolation or quarantine locations to and from health care facilities.

Title II—Improving Public Health Preparedness and Response Capacity

Subtitle A—Addressing Disparities and Improving Public Health Emergency Responses

IDSA supports this subtitle and recognizes the significant role of social determinants of health in determining health outcomes. The COVID-19 pandemic starkly highlighted longstanding health inequities, and the federal government must provide leadership and resources for efforts to reduce health disparities. We appreciate that in addition to authorizing new grants in this area, the subtitle also calls for a report from the Department of Health and Human Services to Congress and a GAO study on social determinants of health, as well as a National Academies of Sciences report on health disparities, all of which should help drive a long-term federal commitment to these issues.

IDSA also notes that ensuring the availability of health care providers focused on biopreparedness and infectious diseases in all communities is critical to reducing health disparities in underserved communities that currently lack access to such providers. It is further important to diversify the health care workforce, including health care professionals in the fields of biopreparedness and infectious diseases.

Subtitle B—Improving Public Health Data

IDSA supports this subtitle to improve the availability of infectious diseases data (particularly demographic data to aid in the identification of at-risk populations and potential health disparities) and to strengthen and expand activities related to advanced molecular detection and genomic

sequencing of pathogens. We appreciate the particular attention to the need to support rapid and accurate reporting of laboratory test results during a public health emergency. Better deploying novel diagnostic techniques and genomic sequencing capabilities for routine use in our communities will also help ensure the readiness of these technologies and public health and health care personnel in future emergencies.

IDSAs notes that while surveillance is a public health activity, successful surveillance and data collection require partnerships with health care facilities, and personnel in health care facilities to diagnose patients and collect and report data. Ongoing shortages of physicians, clinical laboratory professionals, infection preventionists and other health care professionals to perform this work will limit our ability to strengthen surveillance and data collection.

Subtitle C—Revitalizing the Public Health Workforce

PRIORITY RECOMMENDATION: INCLUDE THE BIO PREPAREDNESS WORKFORCE ACT (S. 3244)

While IDSAs supports the current sections in this subtitle, we believe that the discussion draft's failure to address significant workforce shortages in the fields of biopreparedness and infectious diseases is a significant shortcoming that will seriously jeopardize our nation's preparedness and impede the successful implementation of several provisions in this discussion draft. Ensuring the availability of our public health workforce, community health workers and volunteers is extremely important, but it is equally important to ensure a sustainable biopreparedness and infectious diseases workforce in our health care facilities to perform unique and essential activities to prepare for, avert and respond to pandemics, including:

- Develop and update facility response plans and protocols;
- Collaborate with state and local health departments;
- Train health care facility personnel;
- Purchase and manage personal protective equipment and other bioemergency equipment;
- Execute readiness assessments;
- Set up patient triage areas of a health care facility;
- Communicate with the public;
- Perform infection prevention and control;
- Track preventable infections in health care facilities;
- Develop and validate diagnostic tests; and
- Conduct antimicrobial stewardship to ensure that treatments for infectious diseases are used appropriately to yield optimal patient outcomes.

Biopreparedness and infectious diseases health care professionals face significant recruitment challenges and shortages, as the statistics below illustrate.

- More than [208 million Americans live in areas with little or no access to an ID physician](#), and the distribution of ID physicians is geographically skewed. Thus, rural Americans are less likely than their urban counterparts to have access to ID physicians.
- Only 70% of infectious diseases training programs were able to fill all their slots in 2021 (down from 75% in 2020), while many other specialties were able to fill all their training programs.
- The [average medical student debt](#) of \$241,900 drives many physicians away from infectious diseases and toward more lucrative specialties.

- At least [25% of health care facilities have reported a vacant infection preventionist position](#), with more than half of long-term care facilities seeing an infection preventionist leave within the last 24 months. These gaps will likely continue to be a challenge in the future as well, as 40% of the infection preventionist workforce will be entering retirement age within the next 10 years.
- Clinical microbiologists, who are central to diagnostic testing, were in short supply before the current pandemic. Results of a [survey](#) published in 2019 showed a total vacancy rate in this area of 10.14%, with a staff vacancy rate of 10.56% and a supervisor vacancy rate of 6.96%. Results also revealed that 17.38% of microbiology department employees are expected to retire in the next 5 years.

We strongly encourage you to include the bipartisan BIO Preparedness Workforce Act in the PREVENT Pandemics Act. This workforce bill would address financial barriers that prevent individuals from pursuing careers in biopreparedness and ID by providing loan repayment to health care professionals, including physicians, pharmacists, physician assistants, advanced practice registered nurses, clinical laboratory professionals and infection preventionists, who spend at least 50% of their time engaged in biopreparedness and response activities anywhere in the U.S., or health care professionals, including physicians, pharmacists, physician assistants, advanced practice registered nurses, clinical laboratory professionals and dentists, who spend at least 50% of their time providing ID care in medically underserved communities and federally funded facilities. A goal of the program will be to increase the number of ID and biopreparedness health care professionals from populations currently underrepresented in medicine.

Subtitle D—Improving Public Health Responses

Sec. 231. Centers for public health preparedness and response. IDSA supports this section, acknowledging the importance of translational research and dissemination of findings to support ongoing improvements to preparedness. IDSA notes that many of the activities described in this section are examples of activities that are best performed by partnerships across public health and health care. Ensuring a health care workforce trained in biopreparedness and infectious diseases will allow these centers to maximize their potential.

Sec. 232. Vaccine distribution plans. IDSA supports this section, as tracking vaccine distribution helps identify challenges and best practices to facilitate rapid, efficient and equitable distribution of vaccines during pandemics.

Title III—Accelerating Research and Countermeasure Discovery

Sec.301. Research and activities related to long-term health effects of SARS-CoV-2 infection. IDSA supports this section and agrees that there is still a great deal to learn about the long-term health impacts of COVID-19 and a significant need for more research to inform optimal management of patients experiencing long-term health impacts of COVID-19. Clinicians with expertise in infectious diseases, particularly those located in rural areas and other communities heavily impacted by COVID-19, will be crucial to the success of this research as well as the dissemination and implementation of findings. Addressing workforce shortages in these areas is essential.

Sec. 302. Research centers for pathogens of pandemic concern. IDSA supports this section to advance the development of medical products for viruses with pandemic potential. This provision will help speed the availability of new life-saving tools for future pandemics.

Sec. 303. Improving medical countermeasure research coordination. IDSA supports this provision, which will help ensure that the best surveillance and epidemiological data are regularly informing medical countermeasure research to help strengthen our preparedness for emerging threats.

Sec. 304. Accessing specimen samples and diagnostic tests. IDSA supports this section, recognizing that increasing access to specimen samples will expand capacity for developing and validating new diagnostic tests. IDSA also supports allowing HHS to contract with public and private entities to improve the rapid development and availability of diagnostic tests to support public health responses. **IDSA recommends that you insert “, including academic clinical laboratories,” (page 125, line 23) after “appropriate entities” to provide an example of an entity HHS may partner with related to testing.** These laboratories were among the first to develop and validate COVID-19 diagnostic tests and remain an integral part of the backbone of our national testing capacity. IDSA also notes that clinical microbiologists are central to diagnostic test development, validation and clinical integration, and this workforce is experiencing significant shortages that must be addressed.

Title IV—Modernizing and Strengthening the Supply Chain for Vital Medical Products

IDSA supports Title IV to strengthen the Strategic National Stockpile (SNS), domestic manufacturing surge capacity for medical countermeasures and the supply chain for medical products. Limited supplies of COVID-19 treatments and diagnostic tests have presented ongoing challenges throughout the pandemic. Significant health care resources are expended to optimally manage limited supplies to ensure they are directed to the patients with the greatest need while leaving many other patients without access. We agree with the need to identify manufacturing vulnerabilities and build in redundancies to prevent shortages of key products. Shortages of personal protective equipment and testing supplies significantly hampered our response to COVID-19, risking the safety of our health care personnel and limiting our ability to diagnose and track infections.

Throughout the COVID-19 pandemic, IDSA has repeatedly heard from members working in state and local health departments and hospitals regarding confusion about how to access medical products from the SNS and other medical countermeasures. Improving communication and transparency will greatly benefit frontline responders and allow them to better serve their patients and communities. Grants to support state stockpiles are very important, as most states do not have the resources to maintain their own stockpiles without federal support.

Title V—Enhancing Development and Combating Shortages of Medical Products

Sec. 501. Advancing qualified infectious disease product innovation. IDSA greatly appreciates the inclusion of a provision aimed at combating antibiotic resistance in the discussion draft. IDSA

supports this section to expand qualified infectious disease product (QIDP) eligibility to include biologics, recognizing that biologics may play a helpful role in treating antibiotic-resistant infections.

Combating antibiotic resistance is central to strengthening our pandemic preparedness, and resistant infections have complicated our response to COVID-19. A large [study](#) of 148 hospitals across 17 states found that COVID-19 surges negatively impact rates of antibiotic-resistant infections. Specifically, from March through September 2020, the study found a 24% increase in hospital-onset multidrug-resistant infections. At the same time, another [study](#) found that more than 77% of patients with COVID-19 were prescribed antibiotics, despite most of these patients not having a secondary bacterial infection. These findings underscore the need for novel antibiotics and investments in stewardship programs to guide their appropriate use. More broadly, outside of the context of COVID, any event involving mass hospitalizations and especially high levels of ventilator use would carry a significant risk of secondary infections, particularly for patients with weakened immune systems. For example, CDC found that [secondary infections claimed between 29% and 55% of the 300,000 lives lost during the 2009 H1N1 pandemic](#). Also, while COVID-19 was a viral public health emergency, the next pandemic could be bacterial or fungal in nature, and we are woefully unprepared.

QIDP status, while helpful, has proven to be insufficient alone to sustain antibiotic research and development. Most large pharmaceuticals have left the space, and since 2019, two small biotech companies focused on antibiotic R&D filed for bankruptcy. Factors unique to antibiotics – namely, short duration of use and the need to use them judiciously to prevent the development of resistance – make it extremely difficult for companies to earn a return on investments in antibiotic innovation.

PRIORITY RECOMMENDATION: INCLUDE THE PIONEERING ANTIMICROBIAL SOLUTIONS TO END UPSURGING RESISTANCE (PASTEUR) ACT (S. 2076) IN THE PREVENT PANDEMICS ACT

The bipartisan PASTEUR Act offers an innovative solution to AMR challenges. First, the bill would create a subscription model for novel antibiotics through which the federal government may enter into contracts with novel antibiotic developers and pay a set fee for a supply of novel antibiotics regardless of the quantity of antibiotics used. This approach pays for value over volume and provides antibiotic developers with the predictable return on investment needed to fuel innovation. Second, the PASTEUR Act would establish a grant program to support antibiotic stewardship programs in hospitals, with priority given to rural, critical access and safety-net hospitals. These programs are highly effective at optimizing antibiotic use, reducing resistance and improving patient outcomes, yet they are typically under-resourced. During the COVID-19 pandemic, stewardship programs also took on the responsibility of managing the complex administration of COVID-19 therapeutics.

Sec. 502. Modernizing clinical trials. IDSA supports this section, particularly the focus on decentralized clinical trials, which we agree will help foster more diverse participation in clinical trials and expand access to clinical trials to patients who do not live close to a large academic medical center. IDSA notes that the successful inclusion of broader patient populations in clinical trials will require health care professionals in all communities to identify and enroll patients in trials. Additional policies are needed to address workforce shortages and ensure providers are located in communities with the greatest need.

Sec. 503. Accelerating countermeasure development and review. IDSA supports this provision to help ensure that safe and effective therapeutics are appropriately reviewed and made available to patients as rapidly as possible.

Sec. 504. Third-party test evaluation during emergencies. IDSA supports this provision, recognizing that FDA consultation with third parties can allow diagnostic tests to be much more rapidly evaluated and made available for use during public health emergencies.

Sec. 507. Increasing EUA decision transparency. IDSA supports this section to help ensure FDA shares more safety and effectiveness information with the public about products authorized for emergency use. We greatly appreciate the heroic efforts of FDA to rapidly and thoroughly review products during the COVID-19 pandemic to speed patient access to life-saving tools. However, limited public availability of safety and efficacy data contributed to delayed uptake and uneven use of some COVID-19 therapeutics and hampered the ability of professional societies to develop clinical guidelines. Increased access to data will greatly improve patient care.

Sec. 509. GAO study and report on hiring challenges at FDA. IDSA supports this section to help ensure sufficient staffing at FDA to carry out its mission.

Sec. 518. Advanced manufacturing technologies designation pilot program. IDSA supports this section and notes that this pilot program could be used to provide much needed support for the manufacturing of generic antibiotics. Generic antibiotics commonly used to treat serious infections have been in short supply for several years due to supply chain challenges. Many have a single manufacturer and rely on ingredients with limited availability. There is very little profit opportunity in this field, making it difficult to attract private investment. Many private companies hoping to bring new antibiotics to the market go bankrupt before they can. In a 2016 survey of infectious diseases physicians, 70% reported modifying their antimicrobial of choice in the previous two years due to an antimicrobial drug shortage. This resulted in the use of broader-spectrum agents (75% of respondents), more costly agents (58%), less effective second-line agents (45%) and more toxic agents (37%). Widespread antibiotic shortages negatively impact patient outcomes and are likely contributing to the development of antibiotic resistance.